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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,724	03/10/2000	Lone Wolinsky	247/212	5199

23639 7590 07/30/2003

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SAN FRANCISCO, CA 94111-4067

EXAMINER
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BUI, VY Q

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/30/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/522,724

Applicant(s)

WOLINSKY ET AL.

Examiner

Vy Q. Bui

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 12-15, 21, 23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 12-15, 23 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 21 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

Election without traverse as acknowledged in previous "Office Action" (paper 7) remains effective. Claim 23 is dependent to claim 12, which is directed to the non-elected invention and is not examined.

Claim 26 is directed to the non-elected invention and is not examined.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-6, 21 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over CIMOCHOWSKI et al (5,967,986).

As to claims 1-3, 21 and 25, CIMOCHOWSKI discloses sensor 220 attached to an outer surface of stent 222 by adhesive 228 through hole/opening 224 (Fig. 19; column 22, lines 53-56). As defined by the reference, an endoluminal implant includes a stent/stent-graft (abstract, lines 9-13; column 4, lines 21-22). CIMOCHOWSKI (Fig. 19) shows explicitly stent 222 as an endoluminal implant. However, according to the reference, the invention in the reference also includes stent-graft and it appears that there is no difference between attaching a sensor to a stent or a stent-graft. Therefore,

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it is reasonable to conclude that CIMOCHOWSKI inherently discloses attaching a sensor to an outer surface of a stent (shown in Fig. 19) or to an outer a stent-graft (not shown). Alternatively, according to CIMOCHOWSKI disclosure, it would have been obvious to one of ordinary skill in the art at the time the invention was made to attach a sensor to an outer surface of a stent-graft so that one biological parameter can be measured. Notice that the functional language in claim 1 indicating that the pressure sensor is for sensing pressure beyond the outer surface of the graft (intended use of the pressure sensor) is carefully considered but the functional language does not specify any structural difference between the reference and the present claimed invention. The patentability of the intended use of the pressure sensor is only fully considered in a method claim.

As to claims 4-6, and 21, CIMOCHOWSKI (Fig. 19-22) discloses an endoluminal implant (including stents or stent-grafts, see abstract, lines 9-13; column 4, lines 21-22) with biosensor 220 (Figs. 19-21A) directly attached to stent 222 by adhesive 228 (column 22, lines 53-56). Biosensor comprises pressure sensors (column 11, lines 26-50; column 22, lines 59-60). CIMOCHOWSKI also discloses that the endoluminal implant can be a self-expanding stent-graft (column 25, lines 41-54) and also can be assisted by balloon (column 25, lines 54-58). Notice that self-expanding stents/stent-grafts and balloon-expanding stents/stent-grafts are well-known endoluminal implants.

### ***Response to Amendment***

The amendment filed on 09/18/2002 under 37 CFR 1.131 has been carefully considered but is ineffective to overcome the CIMOCHOWSKI reference.

The limitation "the biosensor comprising a pressure sensor arranged for sensing pressure beyond the outer surface of the graft" as amended in claim 1 does not specify any structural limitation of the device in the present invention to distinguish the present invention to the CIMOCHOWSKI device.

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**Conclusion**

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pats. 6,159,156/6,416,474/6,475,170 disclose a pressure sensor placed in an aneurysm sac.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2708 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB

July 20, 2003